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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,067	06/28/2002	Mats Paulsson	HLZ-001USRCE	7795

959 7590 09/17/2008

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EXAMINER	
COUNTS, GARY W	

ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
09/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/019,067	PAULSSON ET AL.	
	Examiner	Art Unit	
	GARY W. COUNTS	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-16 and 26-31* is/are pending in the application.

4a) Of the above claim(s) *15,16 and 26-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/22/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/22/08 has been entered.

Status of the claims

The amendment filed August 22, 2008 is acknowledged and has been entered. Currently, claims 13-16 and 26-31 are pending. Claims 15-16 and 26-31 are withdrawn as being directed to a non-elected invention. Claims 13 and 14 are under examination.

Rejections withdrawn

In light of Applicant's amendments to the claims and the cancellation of claim 32, the rejection of claims 13, 14 and 32 under 35 U.S.C 112 first paragraph written description and enablement, are hereby, withdrawn.

In light of Applicant's cancellation of claim 32, the rejection of claim 32 under 35 U.S.C. 112 2nd paragraph is moot and hereby withdrawn.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 13 and 14 are rejected under 35 U.S.C. 102(b) or (e) as being anticipated by Schuppan et al (WO 98/03873 or US 6,319,726).

The WO and US references have the same disclosure. Schuppan et al disclose methods of detecting antibodies from body fluids by means of an immune reaction with tissue tranglutaminase (see '726 abstract). Schuppan et al disclose that the tissue transglutaminase can be human tissue transglutaminase (see '726, col 6, lines 20-22). Schuppan et al disclose that the tissue tranglutaminase can be immobilized and used to detected antibodies in a sample for diagnosing celiac disease (sprue) (gluten sensitive enteropathic autoimmune disease) (see '726, col 3). Schuppan et al disclose that the method is used to detect IgA antibodies.

With respect to the recitation "and at least one other transglutaminase molecule selected from FXIIIA, TGk, TGx, TGe and Band 4.2". Schuppan et al disclose that the antibodies to be detected are IgA antibodies which are against human tissue transglutaminase. These antibodies to be detected are the same as the antibodies detected by applicant (see specification). Thus, the antibodies of Schuppan et al would be cross reactive with other antigens and would inherently be against TGe. As shown by Applicant the IgA antibodies are cross reactive. The specification on page 15 discloses "the results shown support that serum IgA antibodies from patients with CD

and DH react with both human TGc and TGe and further discloses that the serum antibodies from patients with CD and DH is directed against epitopes which are shared by the two transglutaminases". Thus, it is inherent that the IgA antibodies of Schuppan et al are against both human tissue transglutaminase and TGe. Further, as stated above the body of the claim merely requires a step of taking a sample and testing the sample for IgA antibodies against human tissue transglutaminase and at least one other transglutaminase molecule. Thus, for the above stated reasons Schuppan et al reads on the instantly recited claim.

Further, with respect to the recitation "correlating significantly increased amounts of the IgA antibodies as compared to a control sample with a diagnosis of a gluten sensitive enteropathic autoimmune disease, thereby diagnosing a gluten sensitive enteropathic autoimmune disease ". The body of the claim recites an interpretive "correlating" clause that is a non-manipulative step. The clause does not recite any additional active method steps, but simply state a characterization or conclusion of the results of those steps. Thus, for purposes of applying prior art the recitation is not given patentable weight. The process steps that are positively recited merely require taking a sample from a patient and testing the sample for IgA antibodies against human tissue transglutaminase and at least one other transglutaminase molecule. In the instant case, Schuppan et al performs every active method step and when every active method step has been performed the prior art method is met. Further, a non-manipulative step to recognize that such steps may constitute an inherent result of a known process and that an inherent result should be treated like any other inherency even a newly

discovered one namely an unpatentable distinction over the prior art. "Newly discovered results of known process are not patentable because such results are inherent" in the prior art. Bristol-Meyers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1376 (Fed. Cir 2001). Nevertheless, it is noted that Schuppan et al does teach determining the antibodies in the sample and comparing them to a control and shows that the antibodies are increased to that of the control (example 2, Schuppan et al). For the reasons stated above Schuppan et al reads on the instantly recited claims.

Response to Arguments

3. Applicant's arguments filed 08/22/08 have been fully considered but they are not persuasive.

Applicant argues that Schuppan et al fail to teach or suggest a diagnosing a gluten sensitive enteropathic autoimmune disease (e.g. dermatitis herpetiformis, AI haemolytic anaemia, AI thrombocytopenic purpura, AI thyroid diseases, and atrophic gastritis-pernicious anaemia, Crohn's disease, colitis ulcerosa, Goopasture syndrome, IgA nephropathy or IgA glomerulonephritis, myasthenia gravis, partial liopdystrophy, polymyosisits, primary biliary cirrhosis, primary sclerosing cholangits, progressive systemic sclerosis, recurrent pericarditis, relapsing polychondritis, rheumatoid arthritis, rheumatism, scacoidosis, Sjogren's syndrome, SLE, splenic atrophy, type I (insuling-dependent) diabetes mellitus, diabetes mellitus of other types, Wegener granulomatosis, ulcerative colitis, vasculitis (both systemic and cutaneous), and vitiligo) comprising taking a sample from a patient, testing the sample for IgA antibodies against human tissue transglutaminase and at least one other transglutaminase molecule

selected from the group consisting of a-subunit of factor XIII, TGk, TGx, TGe and Band 4.2; and correlating a gluten sensitive enteropathic autoimmune disease. This is not found persuasive because of reasons stated above and further because the recitation "correlating significantly increased amounts of the IgA antibodies as compared to a control sample with a diagnosis of a gluten sensitive enteropathic autoimmune disease, thereby diagnosing a gluten sensitive enteropathic autoimmune disease ". The body of the claim recites an interpretive "correlating" clause that is a non-manipulative step. The clause does not recite any additional active method steps, but simply state a characterization or conclusion of the results of those steps. Thus, for purposes of applying prior art the recitation is not given patentable weight. The process steps that are positively recited merely require taking a sample from a patient and testing the sample for IgA antibodies against human tissue transglutaminase and at least one other transglutaminase molecule. In the instant case, Schuppan et al performs every active method step and when every active method step has been performed the prior art method is met. Further, a non-manipulative step to recognize that such steps may constitute an inherent result of a known process and that an inherent result should be treated like any other inherency even a newly discovered one namely an unpatentable distinction over the prior art. "Newly discovered results of known process are not patentable because such results are inherent" in the prior art. Bristol-Meyers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1376 (Fed. Cir 2001). Nevertheless, it is noted that Schuppan et al does teach determining the antibodies in the sample and comparing them to a control and shows that the antibodies are increased to that of the control

(example 2, Schuppan et al). For the reasons stated above Schuppan et al reads on the instantly recited claims. With respect to the numerous diseases listed above by the applicant it is noted that claim 13 does not require these specific diseases and also even if the diseases were listed in claim 13 Schuppan would still read on the reference for the reasons stated above concerning the interpretive "correlating" clause. Further, it is noted that Schuppan et al also teaches the predominantly latent sprue is frequently accompanied by dermatitis herpetiformis (col 2) and as disclosed by the applicant at page 1 of the current specification both coeliac disease and dermatitis herpetiformis have the same genetic background. Schuppan et al also specifically teaches that the method can be used in the diagnosis of such diseases as pneumonia, glomerulonephritis, virus hepatitis, Morbus Crohn, Colitis ulcerosa Sjoegrens syndrome, Wegener's granulomatosis, rheumatoid arthritis, idiopathic organ fibrosis (col 4).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GARY W. COUNTS whose telephone number is (571)272-0817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ Gary W. Counts/
Examiner, Art Unit 1641

/Mark L. Shibuya, Ph.D./
Supervisory Patent Examiner, Art Unit 1641